

Scientific Coordination, Inc.

Helping Technology Transfer
4629 Cherry Valley Drive
Rockville, MD 20853
06 October 2017

Document Processing Desk (APPL)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Mr. Michael Wagman, PM 4

Subject: Zecken Rollen Tick Tubes
EPA File Symbol 71910-
"Initial Registration Submission"

Dear Mr. Wagman:

Enclosed, please find our Client, Thermacell Repellents, Inc's Application for Pesticide Registration for the subject product using the selective cite-all method. We believe that this application for a new registration meets the criteria for action code R300. Thermacell Repellents, Inc. has assigned this specific registration activity to Scientific Coordination, Inc.

Thermacell have credits, from previous PRIA payment refunds. We would like to apply a portion of these credits toward this activity. The PRIA R300 service fee is \$ 1,582. The credit will, therefore, have \$9315 remaining which our client intends to apply to future submissions (25CSL9F8 - \$263, 25QI1RTA-B - \$10, 25QLQRG6-B - \$14,602 and 25RI60UL-B - \$10 less a recent 71910-3 R340 PRIA submission for \$3,998).

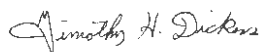
Included are the following:

1. Application for Pesticide Registration, EPA Form 8570-1
2. Confidential Statement of Formula, (1 basic, 1 alternate) 8570-4
3. Formulator's Exemption Statement, 8570-27
4. Certification with Respect to Citation of Data, 8570-34
5. Data Matrix (3 pages), 8570-35
6. Proposed Product Label
7. Series 830 - Product Chemistry Data –Volume 1 of 1 [MRID# 504100]

Please note, the 2-week accelerated storage stability study was begun, initially, in support of the European version of this product which will contain 7% active ingredient. The same formulation and formulating process will be used for the USA version at 7.4% AI. The samples initially assayed high in this study and following 2-weeks at 54°C remained stable.

As you have questions or comments regarding this submission, please do not hesitate to contact our Associate, Lawrence Feller, at lawrence.feller@lflrconsulting.com or 610-863-1023.

Sincerely,



Timothy H. Dickens, Ph.D.
Authorized Agent



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 71910 -	2. EPA Product Manager Michael Wagman	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zecken Rollen Tick Tubes	PM# 4	
5. Name and Address of Applicant (Include ZIP Code) Thermacell Repellents, Inc. c/o Scientific Coordination, Inc. 4629 Cherry Valley Drive Rockville, MD 20853 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 56783-1 Product Name DAMMINIX	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Registration using the Selective-Cite-All Submission method. Included, are draft labeling, Confidential Statement of Formula (Basic), 8570-4, Formulator's Exemption Statement, 8570-27, Certification With Respect To Citation of Data, 8570-34, Data Matrix (3 pages), 8570-35 and Product Chemistry.

We believe that this application for a new registration meets the criteria for action code R300 (New product-only product chemistry review). Further, we have paid the registration service fee of \$1,582 using an existing credit (25QLQRG6-B; \$10,897). For confirmation and/or questions please do not hesitate to contact our Associate, Lawrence Feller, at lawrence.feller@flrconsulting.com or 610-863-1023.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input checked="" type="checkbox"/> Plastic	
				<input checked="" type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) Cardboard Tube	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 6, 12, 24 Pack; .16 oz / 4.5 g ea. tube		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On Packaging	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Timothy H. Dickens, Ph.D.		Title Authorized Agent		Telephone No. (Include Area Code) (301) 570-4390	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Authorized Agent			
4. Typed Name Timothy H. Dickens, Ph.D.		5. Date October 05, 2017			



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address

Thermacell Repellents, Inc. c/o Scientific Coordination, Inc.
4629 Cherry Valley Drive
Rockville, MD 20853

EPA File Symbol/Registration Number

71910 -

Product Name

Zecken Rollen Tick Tubes

Date of Confidential Statement of Formula (EPA Form 8570-4)

Enclosed

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Permethrin Technical

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.**Source****Active Ingredient****Product Name****Registration Number**

Permethrin Technical

Permethrin Technical

Signature
Name and Title

Timothy H. Dickens, PhD, Authorized Agent

Date

October 05, 2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number (301) 570-4390 Thermacell Repellents, Inc. c/o Scientific Coordination, Inc., 4629 Cherry Valley Drive, Rockville, MD 20853	EPA Registration Number/File Symbol 71910 -
Active Ingredient(s) and/or representative test compound(s) Permethrin Technical	Date October 05, 2017
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Outdoor Insecticide (tick control)	Product Name Zecken Rollen Tick Tubes

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 10-05-2017	Typed or Printed Name and Title Timothy H. Dickens, PhD, Authorized Agent
---------------	--------------------	--

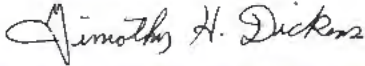


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date October 05, 2017			EPA Reg No./File Symbol 71910 -		Page 1 of 3
Applicant's/Registrant's Name & Address Thermacell Repellents, Inc., c/o Scientific Coordination, Inc., 4629 Cherry Valley Drive, Rockville, MD 20853			Product Zecken Rollen Tick Tubes		
Ingredient Permethrin Technical					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry 830.1550	Chemical Identity	See CSF	Thermacell Repellents, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	See CSF	Thermacell Repellents, Inc.	OWN	
830.1670	Discussion of Formation of Impurities		Thermacell Repellents, Inc.	OWN	
830.1700	Preliminary Analysis	NA	NA	FOR	
830.1750	Certification of Ingredient Limits	See CSF	Thermacell Repellents, Inc.	OWN	
830.1800	Analytical Method to Verify Certified Limits		Thermacell Repellents, Inc.	OWN	
830.6302	Color		Thermacell Repellents, Inc.	OWN	
830.6303	Physical State		Thermacell Repellents, Inc.	OWN	
830.6304	Odor		Thermacell Repellents, Inc.	OWN	
830.6313	Stability	NA	NA	FOR	
830.6314	Oxidizing/Reducing Action	NA	NA	FOR	
830.6315	Flammability	---	---	---	Footnote 1
830.6316	Explosibility	---	---	---	Footnote 2
830.6317	Storage Stability		Thermacell Repellents, Inc.	OWN	
830.6319	Miscibility	NA	NA	FOR	
Signature 			Name and Title Timothy H. Dickens, Ph.D., Authorized Agent		Date 10-05-2017



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			Thermacell Repellents, Inc.	OWN	
			Thermacell Repellents, Inc.	OWN	
			Thermacell Repellents, Inc.	OWN	
			NA	FOR	
			Thermacell Repellents, Inc.	OWN	
			Thermacell Repellents, Inc.	OWN	
			Thermacell Repellents, Inc.	OWN	
			Thermacell Repellents, Inc.	OWN	
			Thermacell Repellents, Inc.	OWN	
			NA	FOR	
			NA	FOR	
			-----	-----	
			-----	-----	
			Thermacell Repellents, Inc.	OWN	
			NA	FOR	
Signature			Name and Title Timothy H. Dickens, Ph.D., Authorized Agent		Date 10-05-2017

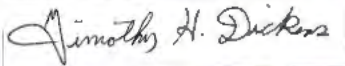


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Ingredient Permethrin Technical					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion Characteristics		Thermacell Repellents, Inc.	OWN	
830.6321	Dielectric Breakdown Voltage	-----	-----	-----	Footnote 3
830.7000	pH	-----	-----	-----	Footnote 4
830.7100	Viscosity	-----	-----	-----	Footnote 5
830.7200	Melting Point	NA	NA	FOR	
830.7220	Boiling Point	NA	NA	FOR	
830.7300	Density		Thermacell Repellents, Inc.	OWN	
830.7370	Dissociation Constant	NA	NA	FOR	
830.7550	Octanol/Water Partition Coefficient	NA	NA	FOR	
830.7860	Solubility	NA	NA	FOR	
830.7950	Vapor Pressure	NA	NA	FOR	
Toxicology 870.1100	Acute Oral LD50 - Rat	44707301	LG Chem, Ltd.	OLD	
870.1200	Acute Dermal LD50 - Rat	44707302	LG Chem, Ltd.	OLD	
870.1300	Acute Inhalation LC50 - Rat	44707303	LG Chem, Ltd.	OLD	
870.2400	Primary Eye Irritation - Rabbit	44707304	LG Chem, Ltd.	OLD	
Signature 			Name and Title Timothy H. Dickens, Ph.D., Authorized Agent		Date 10-05-2017



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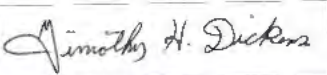
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Ingredient Permethrin Technical					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Thermacell Repellents, Inc.	OWN	
			_____	_____	
			_____	_____	
			_____	_____	
			NA	FOR	
			NA	FOR	
			Thermacell Repellents, Inc.	OWN	
			NA	FOR	
			NA	FOR	
			NA	FOR	
			NA	FOR	
			LG Chem, Ltd.	OLD	
			LG Chem, Ltd.	OLD	
			LG Chem, Ltd.	OLD	
			LG Chem, Ltd.	OLD	
Signature			Name and Title Timothy H. Dickens, Ph.D., Authorized Agent		Date 10-05-2017

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Ingredient Permethrin Technical					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2500	Primary Dermal Irritation	44707305	LG Chem, Ltd.	OLD	
870.2600	Dermal Sensitization	44707306	LG Chem, Ltd.	OLD	
Efficacy -					
810.3400	Tick Buster Containing 7.4% Permethrin: Efficacy Data	265658	Ecohealth, Inc.	OLD	
Footnotes: 1. Flammability: A combustion study has been submitted. 2. Explodability: No explosive ingredients found in product. 3. Dielectric Breakdown Voltage: Not for use around electrical equipment. 4. pH: Non-aqueous formulation. 5. Viscosity: Solid. Not fluid. CITE-ALL (Generic Data): Pesticide Data Submitters List - 109701 Permethrin, Jul 5, 2017 Edition.					
Signature 			Name and Title Timothy H. Dickens, Ph.D., Authorized Agent		Date 12-07-2015

Applicant's/Registrant's Name & Address

Thermacell Repellents, Inc., c/o Scientific Coordination, Inc., 4629 Cherry Valley Drive, Rockville, MD 20853

Product

Zecken Rollen Tick Tubes

Ingredient	Permethrin Technical
-------------------	----------------------

[illegible]

Footnotes:

1. Flammability: A combustion study has been submitted.
2. Explodability: No explosive ingredients found in product.
3. Dielectric Breakdown Voltage: Not for use around electrical equipment.
4. pH: Non-aqueous formulation.
5. Viscosity: Solid. Not fluid.

CITE-ALL (Generic Data): Pesticide Data Submitters List - 109701 Permethrin, Jul 5, 2017 Edition.

Signature

Timothy H. Dickens

Name and Title

Timothy H. Dickens, Ph.D., Authorized Agent

Date _____

12-07-2015



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Ingredient Permethrin Technical					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LG Chem, Ltd.	OLD	
			LG Chem, Ltd.	OLD	
			Ecohealth, Inc.	OLD	
Signature			Name and Title Timothy H. Dickens, Ph.D., Authorized Agent		Date 12-07-2015

Zecken Rollen Tick Tubes

[Alternate Brand names:

1. Thermacell Tick Control Tubes
2. Tick Control Tubes by Thermacell
3. Tick Control Tubes
4. Tick Stop, Tick Control Tubes]

[A TICK TOXICANT

1. As an aid in the control of ticks (that may carry Lyme disease) [that infest mice and nests of mice found around yards, play areas, parks, brush, paths and in woodlands].
2. For Treatment Around Yards and Wooded Lots
3. Easy to Use.
4. Apply [twice a year] [2X a year] [once in the spring and once in the summer].
5. Place in Brush, Woodpiles, Rock Walls and Flower Beds.
6. 6 [Product Name] [tubes] treat approximately 5,500 sq. ft.
7. [X] tubes treat approximately - [X] sq. ft. [of mouse habitat] [including] [brush-covered areas, woodlands, flower beds, woodpiles, rock walls] [per application] {Note to Reviewer: application rate remains the same but number of tubes and coverage area can be adjusted based on package size}
8. Place tubes no greater than 10 yards apart from each other.]

Active Ingredient:

Permethrin* 7.4%

Other Ingredients: 92.6%

Total 100.00%

Keep Out of Reach of Children

CAUTION

See [back] [side] [bottom] [panel] [and insert] for additional precautions

Net Contents: [X] tick control tubes at [X] oz (x grams) each

Total: [X] oz ([X] grams)

EPA Reg. No. 71910-

EPA Est. No. 92674-BGR-01

Manufactured in Bulgaria

©Thermacell Repellents, Inc.

26 Crosby Drive

Bedford, MA 01730

Toll Free: 1-866-753-2837

Email: tickhelp@thermacell.com

{NOTES TO THE REVIEWER:

[] Denotes alternate/optional verbiage

{ } Denotes verbiage not printed on market labeling

= Number

Tubes may also be referred to as "tick tubes or "[Product name] Tubes"]

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

First Aid

If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may call 1-800-222-1222 for emergency medical treatment information. [For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-866-753-3837, Monday through Friday, 8:30 AM to 4:30 PM EST. After 4:30 PM, call your poison control center.]	

{Note: The first aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Combustible. Do not use or store near excess heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[See leaflet inside box for usage directions.]

{Additional, optional text and graphics to provide clarification to the user on how the product works}



[How Tick Control Tubes Work] [How it Works]

1. Ticks feed on mice.



2. Tick Control Tubes are filled with [cotton][material] treated with permethrin insecticide.



3. Mice collect the treated [material] [cotton] and use it to line their nests.



4. Ticks feeding on the mice are exposed to the [material treated with] permethrin insecticide.]

FOR OUTDOOR APPLICATION ONLY. For the reduction of ticks associated with the mice that serve as reservoirs for pathogens causing Lyme disease and babesiosis. Ticks feeding on these animals become infected and may transmit disease to humans, dogs, and horses.

For best results, place tubes flat on the ground in all brush-covered and wooded areas to be treated. Do not exceed the maximum distance of 10 yards between tubes in any direction. Limit treatment areas to those areas inhabited by mice, and need not include mowed lawns or open grasslands. Position tubes so that mice have access to the open ends. Product works best if not covered by leaves or other material.

FOR TREATMENT AROUND YARDS: Place tubes within 1 yard of the edge of mowed lawn, in flower gardens, under bushes and along fences, wherever mice may reside. For complete coverage, apply tubes to all brush-covered or wooded areas within 50 yards surrounding the yard area to be protected.

FOR TREATMENT OF WOODLOTS: Place tubes in a contiguous array (such as a grid design), with no more than 10 yards between tubes in any direction. For complete coverage, apply tubes up to the brush-covered edge surrounding the woodlot. Tubes placed near thickets or rotting logs within the woodlot will be more effective than those placed in more open woodland terrain.

Tubes may be applied anytime between April 1 and mid-September, but should be applied at least twice a year. For best results, apply just prior to the feeding activity periods for nymphal (May-June) and larval (August-September) ticks. Tubes may also be replaced when nesting material is completely removed. The tubes and unused cotton are biodegradable and may be left in the application site.

Storage and Disposal

Do not contaminate water, food or feed by storage.

Pesticide Storage: Store at room temperature in an area inaccessible to children and pets.

Pesticide Disposal and Container Handling: If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions.

[100% Satisfaction Guaranteed. At [Company Name] [Product Name], we stand behind our products and our quality. If you are not completely satisfied with your [Product Name] purchase, you may return it to us for replacement or refund.]

[For refund or replacement,] please call customer care at 866-753-3837. To qualify, you must have a receipt and be within a year from the original purchase date to qualify.]